Image Guided Intervention Workshop

NIH / NSF

12-13 September 2002

Summary

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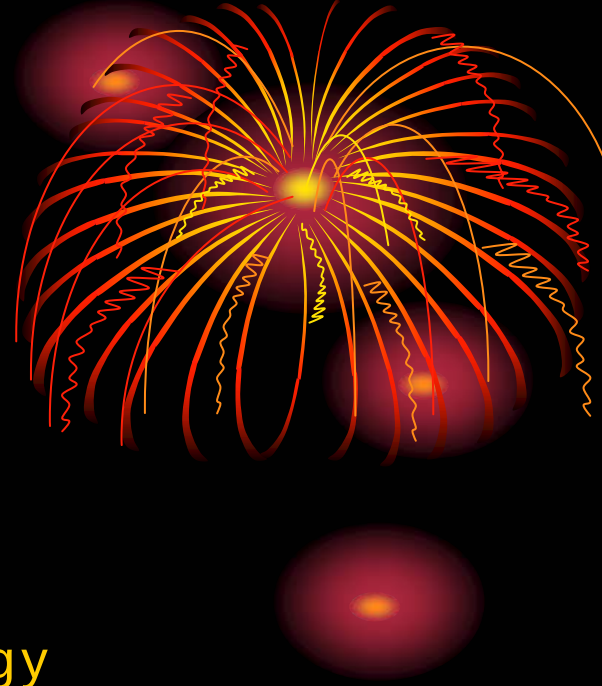
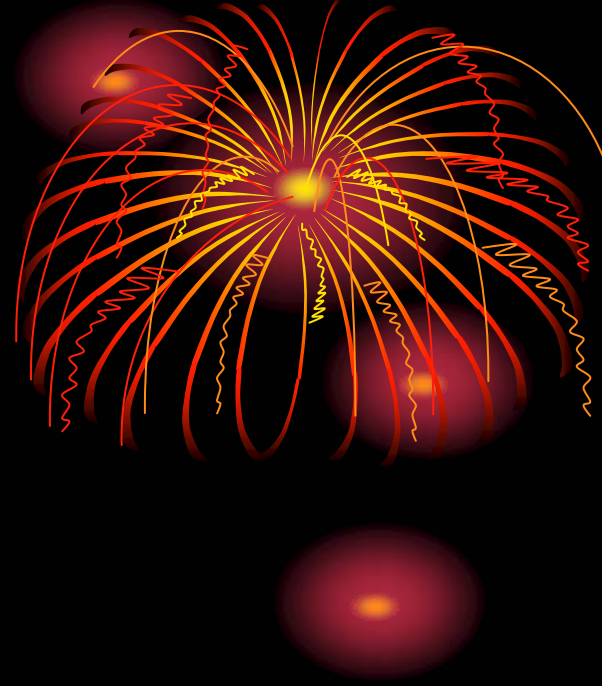
Outline



- Requirements
  - Clinical needs
  - Barriers
- Integration
  - Components - Enabling technology
  - Systems Engineering
- Standards

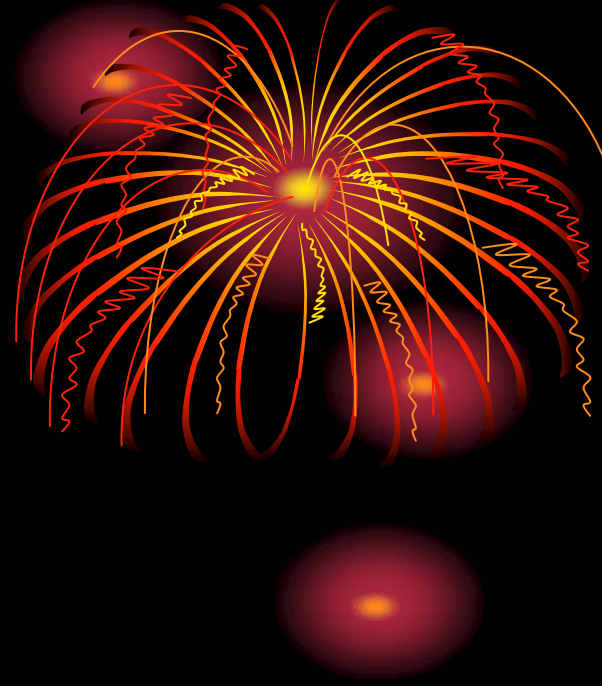
- Clinical domains
  - Neurosurgery
  - Lung
  - Prostate
  - Other cancers
  - Non-oncologic applications

Clinical needs



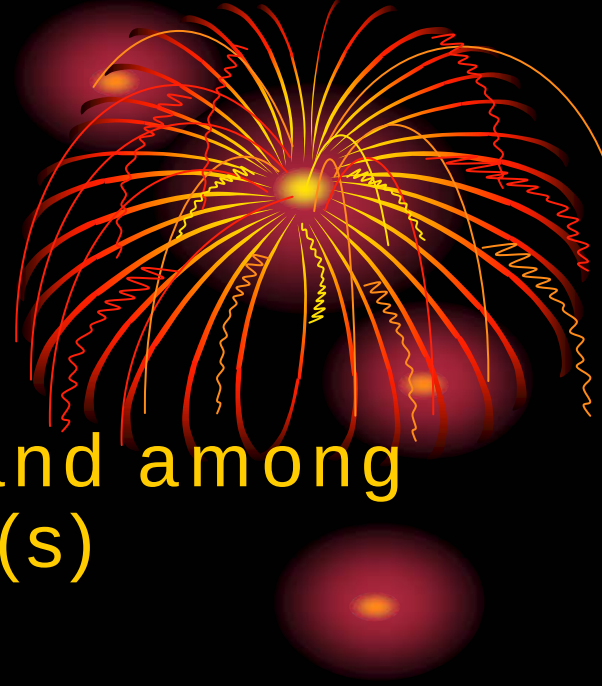
- Pre-trial (IDE from FDA)
- Trials (for FDA approval)
- Target definition
- Speed ("Real time")
- Ease-of-use
- Image update capability
- Visualization
- Variety of end effectors
- Multimodality

Barriers



- Communication
- Champion
- Operator training
- Limited domain of application
- Cost and regulatory barriers
- Complexity
- Lack of standards
- Geography

Integration



- Communication between and among system elements and user(s)
  - Human factors is critical
  - Design for evaluation (QA, RCT, DFSS)
- Integration: technical; workflow
- Plug and play capability (h/w & s/w)
- Move components between systems (to/from centers of development)
- Teleoperation (?)

Status

- Standard of care: resistant to change
  - De facto requirement that any new system must meet/exceed current practice
- Special purpose systems have been successful
  - Simple robot (laparoscopy assistant)
  - Image-guided radiotherapy
  - Stereotactic breast biopsy
- Unable to reuse experience
- Single-center approach to high end requirements

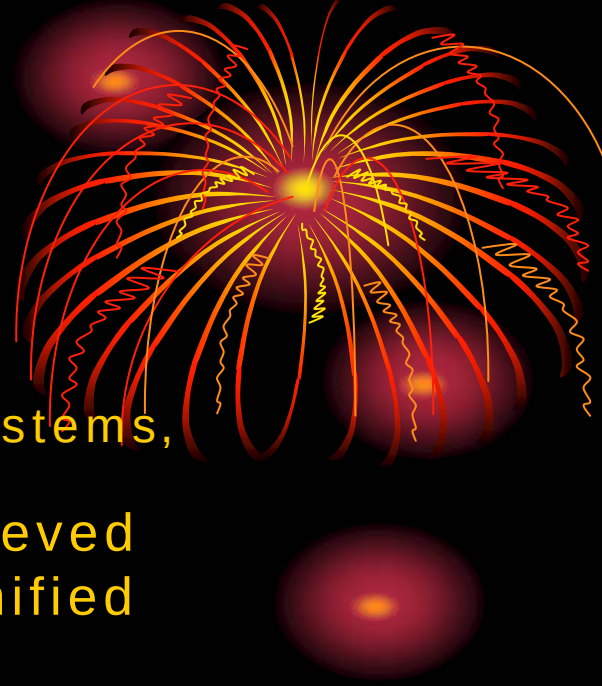
Who needs IGI?

- Customer (patients & family; referring clinicians; payors) demands options
  - Implies that they are selected (tailored) to individual requirements
- Surgeons / interventionalists ... which could ultimately be almost any practioner
  - For example, all dentists perform “interventions” – Will we redefine the role of physicians (blur the line between diagnosis and therapy)?

Axioms

- IGI is “minimally invasive”
- IGI is intrinsically multidisciplinary
- Real time means fast enough that system latency is not a hindrance
- “Good enough”; “least burdensome”; “substantially equivalent” are sufficient to serve real world needs
- Systems are semiautonomous; human operator is ALWAYS included

Common themes



- Communications
  - Between/among people, components, systems, institutions
- Real time – necessary, but seldom achieved
- Combine more & more elements in a unified approach
  - Screen + diagnosis + therapy
  - More…more…more – modalities, displays, robots, etc.
- Manage expectations – since there is strong public interest
- Proof of benefit is necessary
- Continuous improvements
  - Reuse experience, monitor performance, update systems
  - Current practice in engineering of IGI systems is antithesis of “extreme programming” where daily, weekly, monthly… interaction among all participants is the rule

Imperatives

- Must – break out of single institution mold
- Interfaces, standards, communications are key issues
- Must – be “real time”
- More is better, but with lower cost, less complexity, increased ease-of-use, automated...
- Open source software and middleware foster collaboration – suggest that centers should take the lead in persistent virtual infrastructure for IGI
- Should focus on major effect – prevalent diseases in early stage, standards, collaborative science, reduction of operator variability

What we don’t need -

Application domains

- Many: brain, lung, prostate, most body regions + organ systems; variety of pathologies
- Requirements vary according to domain:
  - Willingness of neurosurgeons to champion IGI is impressive and sets the standard
  - In lung, tissue sampling of small screen-detected nodules by “ordinary” radiologists with few complications is major problem
  - In prostate, FN random biopsies are common and target definition is problem
  - Some of the most important potential application domains (e.g., general surgery, oncology surgery, orthopedics, ...) are less well developed

Promising technologies

- Optical, CT, MR, US
  - Especially combined modalities
- IGI treatment planning & simulation
- Synergistic contrast agents and instruments (sensors/effectors)
- Open source and collaborative science infrastructure

Evaluation

- Synonymous with quality assessment; validation
- Implies measurements, common protocols and comparison with established “state of the art”
- Performance, usability, flexibility, extensibility
- Testing should include intended application (e.g., organ system, body region, specific pathologies)
- Standardized tools for evaluation / QA

User Interface

- Familiar and consistent with current practice (e.g., image types)
- Tailored to application
- Present “new” real time images in context
- Haptic OK, but may not be essential
- Can overload the operator - KISS

Next steps (?)

- Translate requirements into specifications
- Verify that specs are achieved
- Clinical applications must guide development
- Inter-institutional collaboration using persistent infrastructure (e.g., grid)
- Limited series of evaluation units into test phase (e.g., evaluation consortium)
  - Common experimental platform replicated at several sites
- The operator/user is key
- Incrementalism is rewarded by regulatory authority; include FDA in the development cycle

Common tasks

- Extraction of geometry from images
- Visualization of instruments in context; multimodality registration
- Target definition
- First guess treatment plan
- Plan optimization
- Plan verification and validation

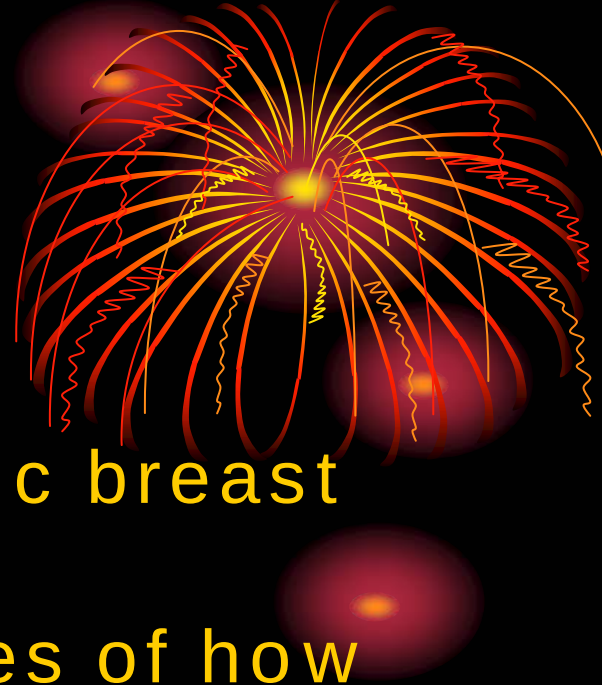
Overall

IGI…blah…blah…blah…blah…blah …blah…Image-Guided….blah….

blah….blah…blah…IGI…blah…blah …blah…Image…blah…blah…

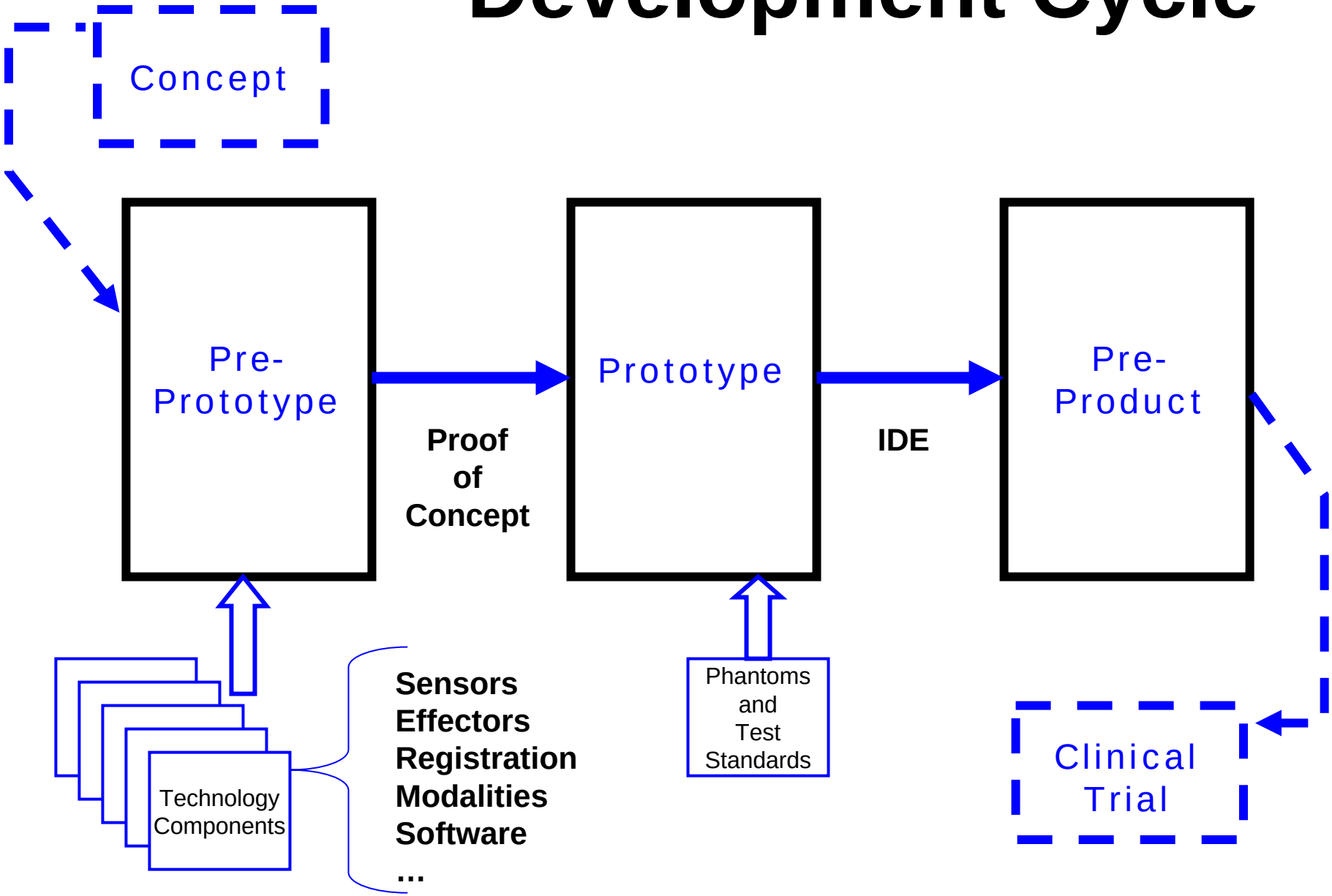
Image Guided Interventions …blah…blah….IGI…

Suggestion

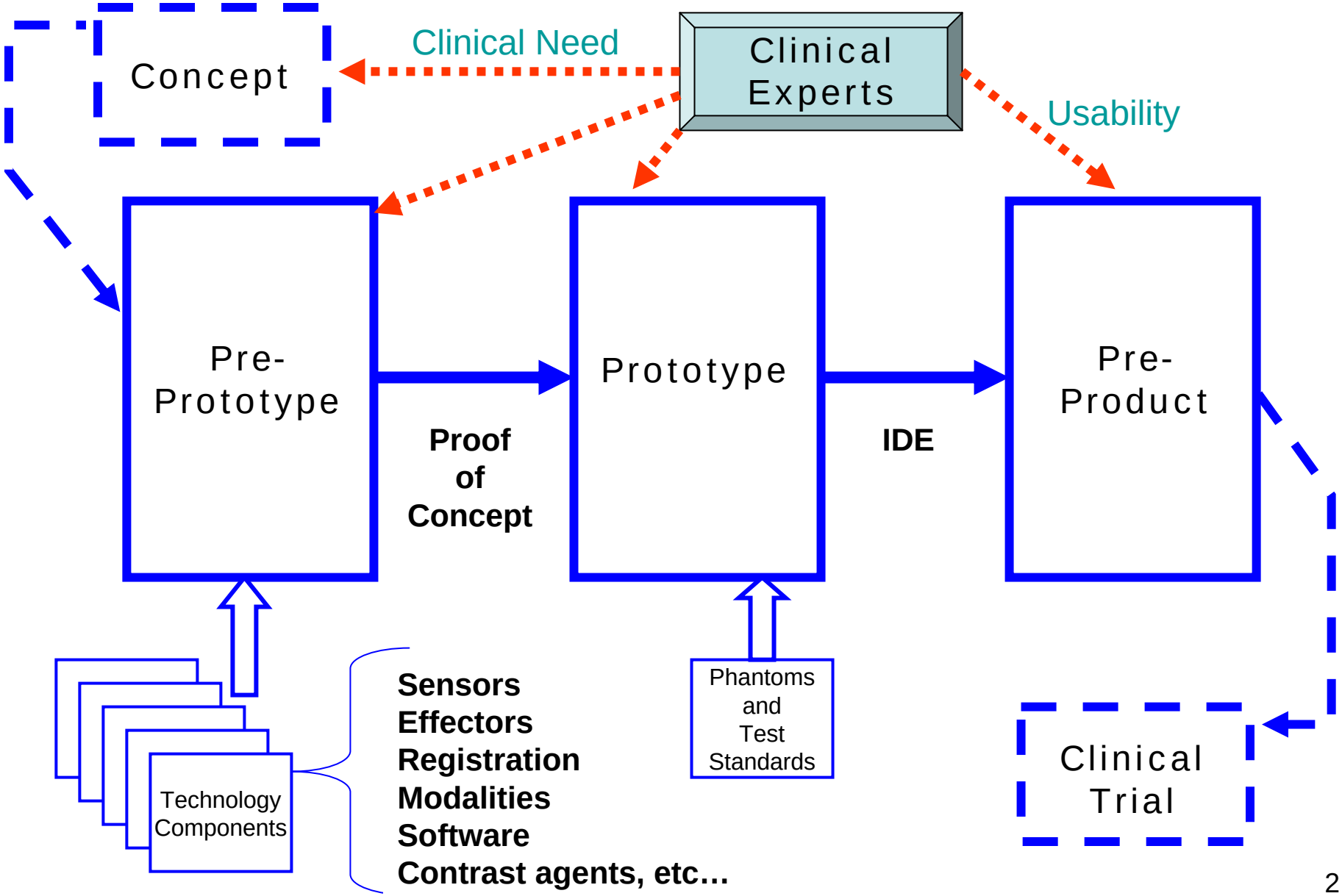


- IGI is successful in clinical radiotherapy and stereotactic breast biopsy
- May be useful as case studies of how IGI evolved to solve real world problems
  - Study and evaluate their experience and disseminate the results outside their narrow domains (to entire IGI community)
- Can we apply their experience in other domains?

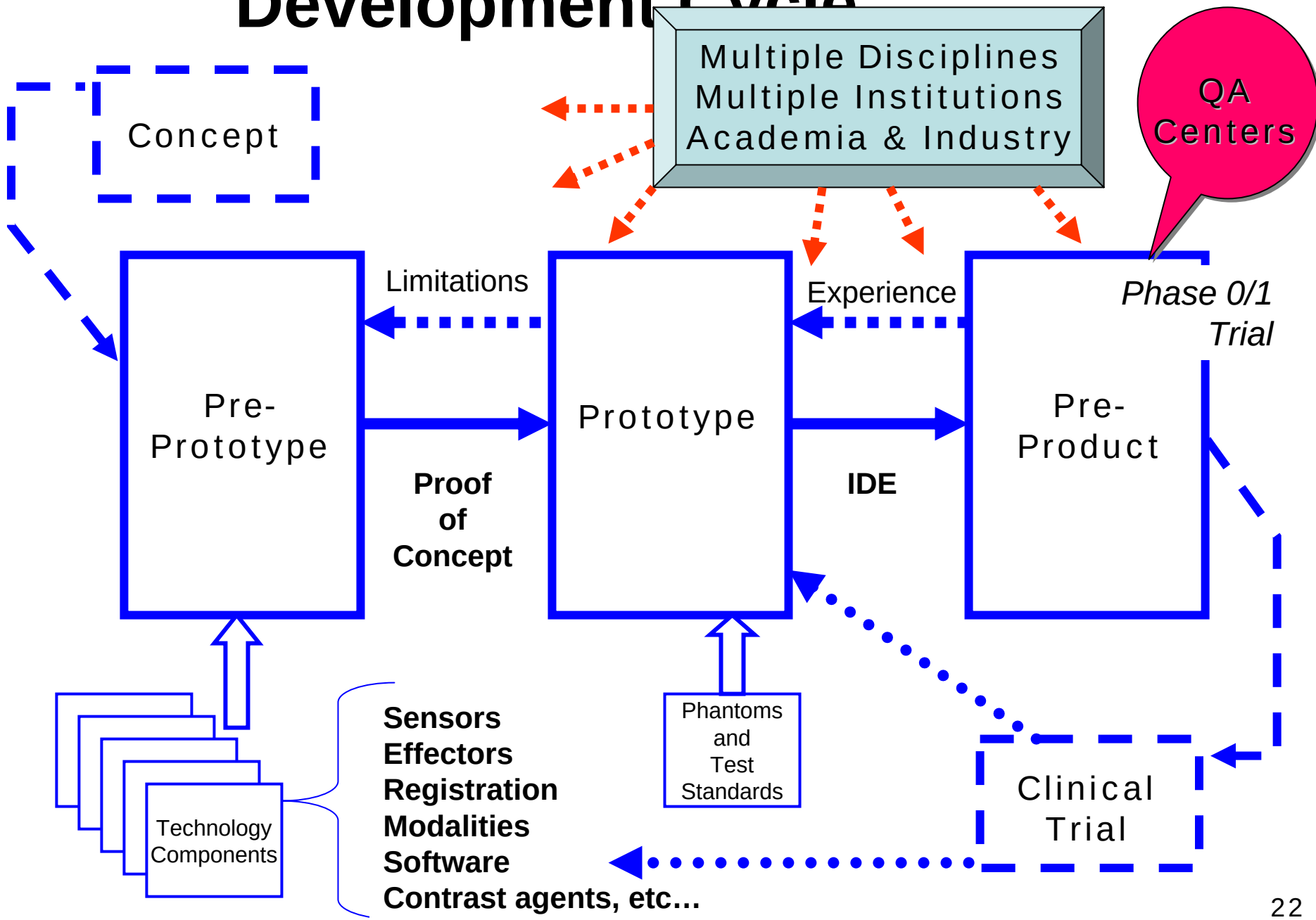
Development Cycle



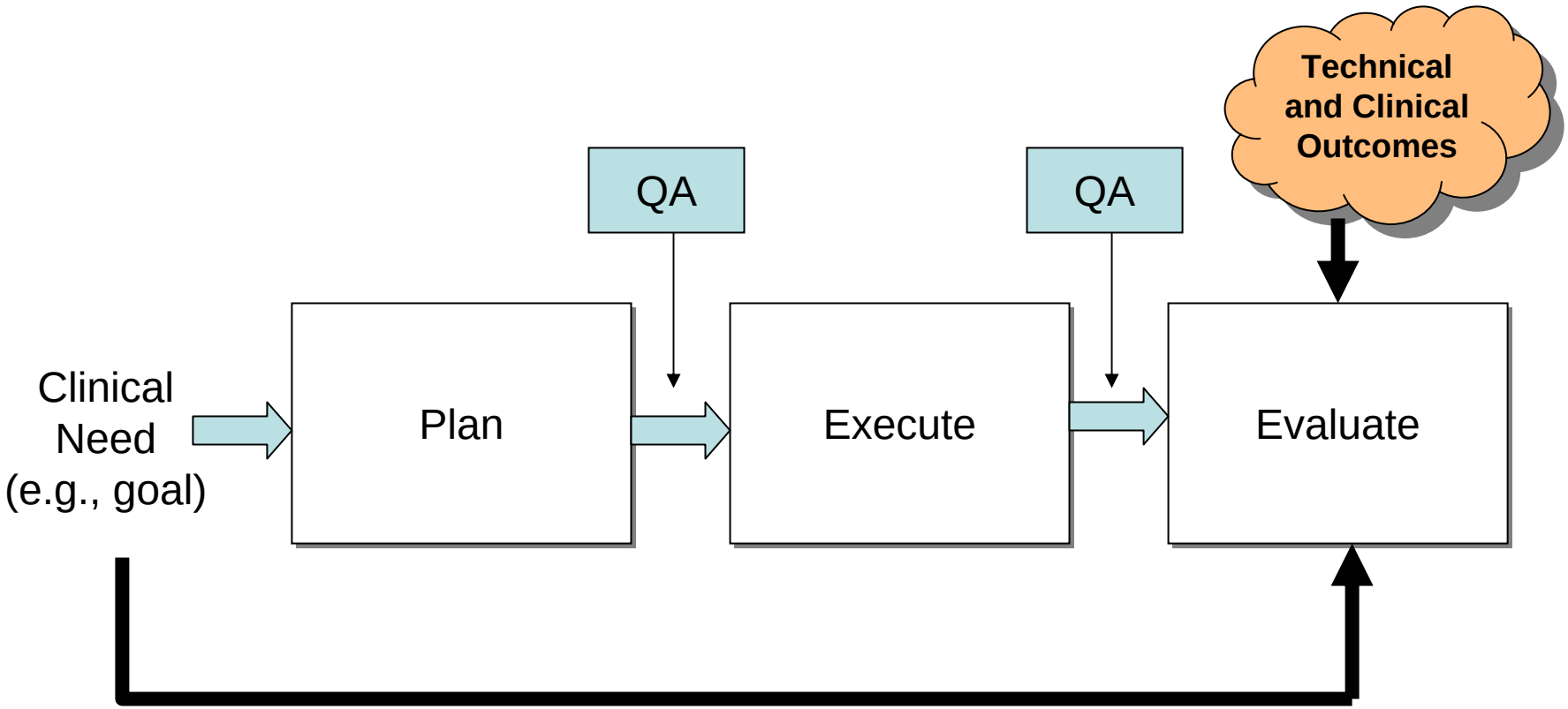
Development Cycle



Development Cycle



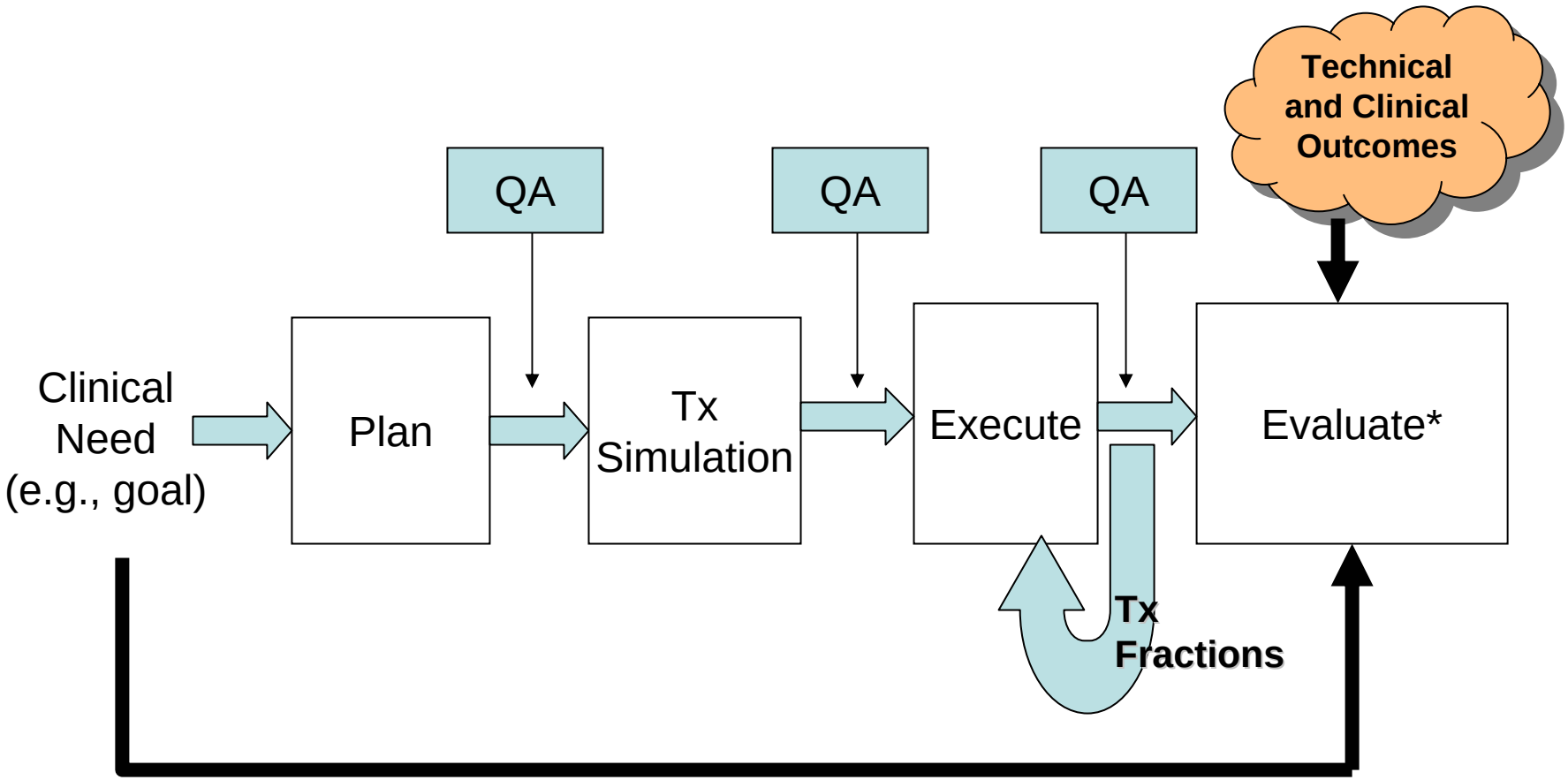
IGI Procedure Paradigm



Certifications:

- Planning system
- Delivery system
- Operator

IGI Paradigm



Certifications:

- Planning system
- Delivery system
- Operator

*At remote QA Center

Motivations

- Quality assurance for IGI
- Interoperability: plan IGI in one institution and perform the procedure in another
- Capture plans and procedures
- Enable reuse of prior experience
- Evaluate (compare) procedures: IGI vs. non-IGI, for example

Multicenter Clinical Trial QA Process

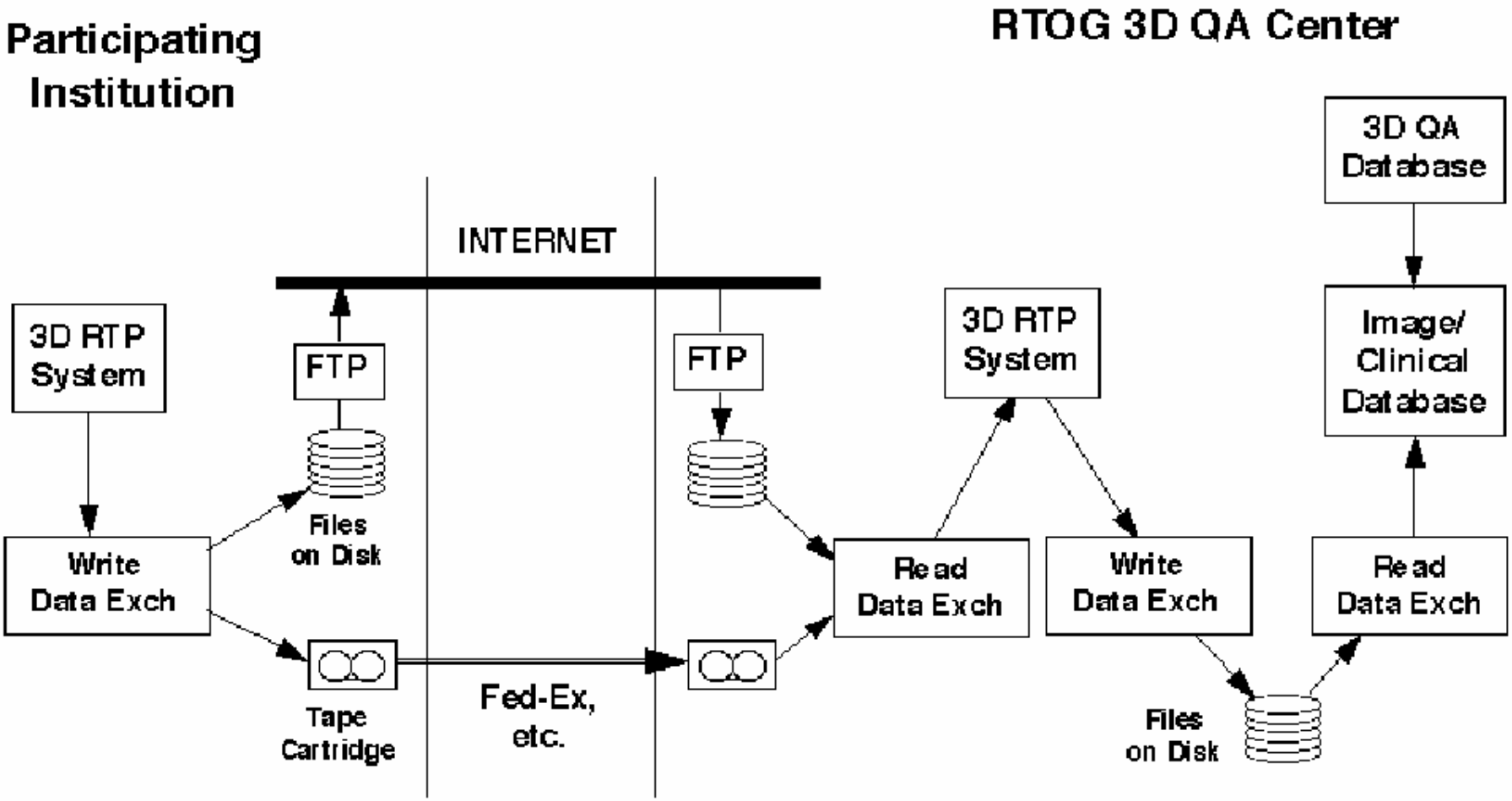
Institution A

Treatment Planning

Institution B

QA Center

Collaborators



Data flow of treatment planning data from RTOG 3DCRT protocol participants to the 3DCRT database.

An Image/Clinical Database for Multi-Institutional Clinical Trials in 3D Conformal Radiation Therapy

W.R. Bosch, T.L. Lakanen, M.G. Kahn, W.B. Harms, Sr., J.A. Purdy

Washington University, St. Louis, MO USA

3D Conformal Radiotherapy Data Exchange Standard

XII th ICCR May 27-30, 1997 465 Salt Lake City, Utah

An Interim Digital Data Exchange Standard For Multi-Institutional 3D Conformal Radiation Therapy Trials

William B. Harms, Sr., B.S., Walter R. Bosch, D.Sc., James A. Purdy, Ph.D.

Washington University, St. Louis, MO, USA

A 3D Quality Assurance Center has been established at the Mallinckrodt Institute of Radiology under the auspices of the Radiation Therapy Oncology Group (RTOG). The role of the 3D QA Center is to provide quality assurance reviews of external beam treatment planning and verification information (TPV) for patients enrolled in RTOG sponsored 3D treatment protocols. This requires a method for participating institutions to submit common format 3D TPV data for review including: volumetric CT image data, normal structure, tumor and target volume contours, digitally reconstructed radiographs (DRR) or simulator (prescription) and portal radiographs, beam geometry, dose distributions, fractionation information and dose-volume histograms (DVH). The original nine institutions involved in the NCI funded 3D Oncology Group Phase I/II prostate dose escalation study (94-06) were the first to implement and use this expanded Specification for exchange of 3D conformal radiation therapy TPV information. Four additional

Common format for 3D data:

- volumetric CT scan data
- contours (normal, tumor, target)
- digital reconstructed radiographs
- or simulator/prescription x-rays
- dose distribution
- beam geometry
- fractionation schedule
- dose-volume histograms

Predecessor of DICOM / RT

Conclusion – 1

- Major progress in IGI since previous plans (e.g., Industry Canada and Scibermed, etc.) were formulated
  - This workshop is timely and fulfills an important need
- Many new and promising IGI component technologies
- Opportunities exist at basic, translational and applied levels in multiple disciplines
- FDA has considered IGI and approval mechanisms are defined
- Several very large and capable groups in major centers dedicated to IGI have been productive in projects with broad potential applicability
- Clinical success with stereo breast bx and IGRT serve as a model of how technology development can change the standard of care in medicine

Conclusion – 2

- This field is evolving rapidly and periodic planning / updates are important
- Training of developers, users, staff is essential
- More collaboration opportunities that bring together surgeons, radiologists, imaging scientists, computer scientists, physicists, etc. are necessary – and strategies were formulated (e.g, web)

What else do you want to know?